

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION  
OPIATE LITIGATION

MDL No. 2804

This document relates to:

Case No. 17-md-2804

*The Montgomery County Board of County  
Commissioners et al. v. Cardinal Health, Inc.,  
et al.*, Case No. 1:18-op-46326-DAP  
("Track Seven")

Judge Dan Aaron Polster

**PLAINTIFF'S OPPOSITION TO KROGER'S MOTION TO EXCLUDE CERTAIN  
OPINIONS OF ANNA LEMBKE, DAVID COURTWRIGHT, AND JAMES  
RAFALSKI**

The Kroger Defendants (collectively, "Kroger") ask the Court to exclude broad sections of Plaintiff's expert reports on the theory that they "violate" this Court's prior *Daubert* rulings, by which Kroger apparently means to suggest that the Court has already ruled on the issues it raises and need only apply its prior rulings.<sup>1</sup> But although Plaintiff agrees that this Court's prior rulings will apply unless different circumstances justify a different result, the rulings in question do not sweep as broadly as Kroger claims, and do not preclude the opinions that Kroger challenges. In particular: (1) this Court has never ruled on the admissibility of the expert opinion of Dr. David Courtwright, so there is no prior ruling to apply here; (2) the expert report for James Rafalski submitted in this case does not contain the opinions that this Court previously ruled were inadmissible in prior

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<sup>1</sup> Kroger offers no other basis for exclusion other than the purported violations of the Court's orders, and has in fact separately moved to "preserve" this Court's prior *Daubert* rulings. See MDL ECF No. 4883.

cases and does not contain improper legal opinions; (3) the Court's prior rulings with respect to Dr. Lembke's opinions were extremely narrow and, with one minor exception, do not apply to the extensive testimony that is the subject of this motion; and (4) with respect to marketing causation, even the Court's narrow ruling should not be applied here because the record in this case is different from the record in Tracks 1 and 3, and demonstrates an appropriate basis for Dr. Lembke's opinions.

### **LEGAL STANDARD**

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court provides an analytical framework for determining whether expert testimony is admissible under Rule 702 of the Federal Rules of Evidence. Rule 702 provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Thus, pursuant to Rule 702, the district court functions as a gatekeeper, ensuring that the expert is qualified, and his or her testimony is both relevant and the product of reliable methods. *Daubert*, 509 U.S. at 589, 590–91, 592–93.

### **ARGUMENT**

#### **I. David Courtwright**

In barely one page of argument, Kroger seeks to exclude opinions offered by Dr. David Courtwright relating to marketing causation on the basis that, as a historian, Dr.

Courtwright is “no more qualified than Dr. Lembke” to opine on marketing causation. Kroger Mot. at 7-8. Despite Kroger’s styling of its motion as one to exclude expert opinions that “violate Orders previously entered by the Court in prior MDL tracks,” *id.* at 1, Dr. Courtwright has never been subjected to a *Daubert* motion in this MDL, there is no prior order with respect to any of his testimony, nor is there any order excluding testimony from any historian. What Kroger is actually asking this Court to do is not to apply its prior orders but rather to *extend* those orders to a different context that the Court has not previously considered. But Kroger fails to demonstrate that this Court’s prior rulings with respect to any other expert are applicable to the opinions offered by *this* expert. And Kroger fails to offer any additional argument for exclusion other than its assertion that the Court’s order with respect to Dr. Lembke is somehow self-evidently applicable to Dr. Courtwright. It is not.

On the contrary, Dr. Courtwright is fully qualified to offer his opinions with respect to marketing causation. Courtwright is currently Presidential Professor Emeritus at the University of North Florida, with a Ph.D. in history from Rice University. He has authored multiple works on the history of drug policy and drug abuse, including one dealing with opioids specifically (*Dark Paradise: A History of Opiate Addiction in America, 1822–1940*), as well as two more recent, general books on the same topic. *See* Courtwright Rep. at 3 (*Forces of Habit* and *The Age of Addiction: How Bad Habits Became Business*). As part of that research, and as part of Courtwright’s proffered opinions here, he has worked extensively with historical sources and materials relating to pharmaceutical marketing and its impacts. *See, e.g.,* Courtwright Dep. 44:20–24 (“[T]here’s certainly information

about pharmaceutical marketing up and down the supply chain in other books that I've published."); *id.* at 45:10–16 ("[I]n [recent] research I continued to make use of pharmaceutical marketing materials . . . because you couldn't really tell the story of the history of psychoactive commerce internationally or globally without research of such materials.").<sup>2</sup>

In short, Courtwright proposes to do for the jury just what he does in his real-world profession as an academic historian: examining and analyzing which historical *causes* produced which historical *effects*. See, e.g., *Pierce v. United States*, 252 U.S. 239, 267 (1920) (discussing professional practice of history as devoted to a determination of which causes produced historical events). The opinions Courtwright proposes to deliver to the jury here are squarely within the subject to which he has dedicated his career, namely, the determinants of U.S. drug policy and drug abuse. The Court should not withhold this professional testimony from the trier of fact on the basis of Kroger's entirely unsupported assertion that a historian is "no more qualified" than an addiction specialist to opine on historical causes of the present opioid epidemic.

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<sup>2</sup> Moreover, Dr. Courtwright has set forth his marketing expertise in a number of depositions and been permitted to present his marketing opinions at trial. See, e.g., *State of Rhode Island, by and through Peter F. Neronha, vs. Purdue Pharma, L.P., et al.*, PC-2018-4555, August 19, 2021, Courtwright Dep. at 251-256; *State of Washington vs. McKesson Corporation, et. al.*, No. 19-2-06975-9, July 26, 2021, Courtwright Dep. at 280:8–284:9; and *State of Florida v. Walgreens*, Case No. 2018-CA-001438, April 11<sup>th</sup> and 12<sup>th</sup>, 2022 Trial Testimony at 257:22-258:11, 263:22-265:3, 384:18-422:16.

## II. James Rafalski

With respect to James Rafalski, Kroger once again seeks to extend, rather than to apply, this Court's prior rulings. This Court has previously excluded certain opinions offered by Mr. Rafalski on the ground that they were improper legal opinions. But Mr. Rafalski heeded the Court's previous ruling and deleted the stricken language from his CT7 report. Kroger now seeks a new ruling that a section of Mr. Rafalski's report not previously challenged falls afoul of the same principles the Court previously applied. It does not.

Kroger seeks to exclude Section L of Mr. Rafalski's CT7 report, arguing that the section contains improper legal opinion. Section L, which has not been the subject of any previous *Daubert* motion, addresses the use, by certain Defendants, of the Chemical Handlers Manual to justify their policies with respect to controlled substances. As Mr. Rafalski explains in his report, the standards under the Chemical Handler's Manual are different from those under the CSA. *See* Rafalski Rep. at 37. Section L notes the difference between "Listed Chemicals" (primarily those used to make methamphetamines) and Schedule II and III controlled substances under the CSA. *Id.* It further notes the difference between orders of "extraordinary size," deemed to be suspicious for Listed Chemicals, and orders of "unusual size," one factor for suspicious orders under the CSA. *Id.* Although Mr. Rafalski uses the infelicitous phrase that use of the "extraordinary size" standard for Listed Chemicals is "not compliant" with 21 C.F.R. § 1301.74(b), which governs suspicious orders of controlled substances, the thrust of his opinion, that the requirements for Listed Chemicals are *different* from the requirements for Controlled

Substances, is *not* a legal conclusion, but rather is grounded in his experience as a DEA agent and his expertise with respect to the CSA. Even if the Court believes that the word “compliant” inappropriately suggests a legal conclusion, it should not preclude Mr. Rafalski from explaining to the jury the important differences between the regulatory framework applicable to “Listed Chemicals” under the Chemical Handlers Manual and that applicable to Schedule II and III controlled substances. Such information will be helpful in assessing any defense based on the Chemical Handlers Manual and does not improperly offer legal conclusions or otherwise invade the province of the Court.

### **III. Anna Lembke**

Finally, Kroger seeks to preclude Dr. Lembke from offering opinions on two broad subjects, marketing causation and pharmacy practice. In both instances, Kroger seeks to apply prior rulings of this Court far more broadly than the original rulings themselves were applied, and to exclude testimony beyond the scope of that found to be excludable in Tracks One and Three. And, in the case of marketing causation, different circumstances here warrant a different result from the rulings in those prior cases. To the extent that the Court decides to adhere to its prior rulings, it should do so narrowly, applying the rulings only to the testimony found excludable in the prior rulings. Moreover, for the reasons below, the Court should depart from its prior rulings and allow Dr. Lembke to offer previously excluded opinions on marketing causation, based on new evidence available in this case that was not before the Court in Tracks One or Three.

**A. The Relief Kroger Seeks Is Overbroad Because the Bulk of Dr. Lembke's Challenged Testimony Is Outside the Scope of This Court's Prior Orders.**

**1. Kroger's Challenge to Dr. Lembke's Marketing Opinions Seeks to Exclude Opinions Previously Permitted by the Court.**

Citing this Court's rulings in Tracks One and Three, Kroger asks the Court to exclude "all opinions or conclusions in Dr. Lembke's Opinion #4, in its entirety." Kroger Mot. at 4. In the alternative, it seeks a narrower ruling that only statements "which draw a causal connection between the Defendants' marketing and an increase in the sale or supply of prescription opioids" are subject to exclusion under the Court's Track One and Track Three rulings. *Id.* Kroger's broader request should be rejected out of hand. In its prior rulings, this Court emphasized the narrowness of its rulings. Thus, in Track One, the Court held:

Lembke may not testify regarding the effect that Defendants' marketing and promotional efforts had on doctors' prescribing practices. . . . [T]his ruling applies narrowly, only to . . . opinions . . . that purport to find Defendants' marketing efforts resulted in or caused increased sales and/or increased prescriptions of opioids. The Court's ruling does not in any way affect Lembke's remaining opinions . . . regarding the inaccuracy of statements and representations in Defendants' marketing materials and other promotional and/or educational efforts. In other words, . . . this ruling does not prevent Lembke from expressing . . . that the Defendants misrepresented the risks and benefits of opioids, and how they did so. Rather, *this ruling applies only to Lembke's opinion regarding a causal connection with respect to pharmaceutical marketing, i.e. that Defendants' marketing efforts resulted in increased sales and/or increased supply of prescription opioids.* Similarly . . . Lembke may testify about the allegedly misleading nature of the materials that she says Manufacturers disseminated to prescribers and how doctors, in general, rely on such information in making prescribing decisions. She may also testify regarding the direct experiences she and her colleagues

have had with Defendants' marketing of opioids. Lembke may not, however, testify as to the causal effect of these actions, *i.e.* she may not opine that these actions caused an increase in the sales and/or supply of prescription opioids.

MDL ECF No. 2549 at 12–13 (internal citation omitted; emphasis added). Similarly, in Track Three, the Court reaffirmed its earlier, narrow holding:

In Track One, the Court ruled that Lembke “is ‘fully qualified’ to opine on matters involving medical facts and science that falls within these areas.” The Court further permitted Lembke to testify about various aspects of the opioid manufacturers’ marketing efforts, and “how doctors, in general, rely on such information in making prescribing decisions.” But the Court ruled *narrowly* that she was not qualified to offer her opinion and testimony “regarding a *causal connection* with respect to pharmaceutical marketing, *i.e.* that Defendants’ marketing efforts resulted in increased sales and/or increased supply of prescription opioids.” . . . The only explicit reference to a new activity that post-dates the Court’s Track One order indicates she gave a lecture at Duke University in 2020 on the subject of “market-driven epidemics.” . . . At the time of its Track One ruling on Lembke, the Court was aware of her expertise in opioid marketing, which is why it allowed her to testify, within limits, on that subject. The Court will not alter its prior ruling.

MDL ECF No. 3953, at 6–7 (internal citations omitted; emphasis in original).

On the basis of these rulings, Kroger’s request for exclusion of the whole of Lembke’s fourth opinion (relating principally to the “paradigm shift” in opioid prescribing as a matter of historical fact and to the opioid supply chain’s false and misleading marketing efforts at the same time as the shift was occurring, *see* Lembke Rep. 27, is facially overbroad: as the Court made explicit, any statement that does not draw a *causal connection* between marketing, on the one hand, and prescribing or supply, on the



other hand, is “not in any way affect[ed]” by the Court’s “narrow[]” ruling. MDL ECF No. 2549, at 12.

Thus, to the extent that the Court finds its prior ruling applicable here, it should exclude only those portions of Section 4 of Dr. Lembke’s report “that purport to find Defendants’ marketing efforts resulted in or caused increased sales and/or increased prescriptions of opioids.” *Id.* Kroger offers no basis—because there is none—for a broader ruling.

**2. Kroger’s Challenge to Dr. Lembke’s Opinions Concerning Pharmacy Policies Goes Beyond the Scope of the Court’s Prior Ruling.**

Kroger’s motion is similarly overbroad with respect to Dr. Lembke’s Opinion #6. Kroger is correct that this opinion includes the statement that pharmacies “failed to provide pharmacists with sufficient time, resources, or incentives to investigate red flags,” *see* Lembke Rep. at 10, and that this Court previously excluded this statement, *see* MDL ECF No. 3953 at 13. Plaintiff thus agrees that Dr. Lembke may not offer this one phrase contained in Opinion 6. But Kroger also seeks to exclude additional portions of Dr. Lembke’s report that elaborate on Opinion 6, specifically statements about the pharmacies’ response to red flags. *See* Kroger Mot. at 5-7 (*citing* Lembke Rep. at 142). There is no basis to exclude these additional statements.<sup>3</sup>

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<sup>3</sup> Plaintiff notes that these additional statements are not contained in Dr. Lembke’s “opinions,” but rather are part of the supporting materials elaborating on and explaining the reasons and bases for the opinions she is offering. To the extent that Dr. Lembke is permitted to offer the opinions set forth in Opinion #6, she should not be precluded from explaining the reasons and bases for them.

The additional challenged statements concerning pharmacy policies and red flags fall within the scope of the material that this Court has previously permitted. In Track Three, the Court recognized Dr. Lembke's expertise to testify about many areas of pharmacy practice, including specifically "on the efficacy and effects of many of Defendants' policies and procedures, such as Defendants' alleged 'ignoring red flags for misuse and diversion including concerns expressed by their own pharmacists.'" MDL ECF No. 3953, at 12-13 (internal citations omitted; original emphasis omitted). The Court reaffirmed this holding at the Track Three trial, agreeing with counsel that Lembke could "testify to the efficacy and effects of the defendants' policies and procedures, such as ignoring red flags." MDL ECF No. 4000, at 622:3-5 (emphasis added). The Court permitted Lembke to "opine as to . . . what red flags were, and whether in her opinion ... the pharmacists were following those red flags or not." *Id.* at 635:18-20. Applying these guidelines, the Court permitted testimony, for example, that "Walmart's policies and procedures were not effective to detect red flags." *Id.* at 636:17-18 (emphasis added). *See also* Order on Daubert Motions, *City & County of San Francisco v. Purdue Pharma*, Case No. 18-cv-07591-CRB (N.D. Cal. May 6, 2022) (ECF No. 1297 at 2) (denying Walgreens' motion, citing this Court's CT3 order, and finding that "Dr. Lembke is qualified to opine on Walgreens' promotional activities and opioid dispensing practices, and her opinions are based on a reliable methodology, as they are 'refracted through the lens of an expert in opioid medication, addiction, and treatment - she is certainly not simply a lay person who read up on the subject'" (quoting *In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804, 2021 WL 4243084, at \*7 (N.D. Ohio Sept. 17, 2021))).

Kroger asserts that the “only direct mention of Kroger in Opinion #6” is Lembke’s statement, under the rubric of pharmacies’ “unique and pivotal position in the opioid supply chain,” that “Kroger pharmacy bonuses were based in part on pharmacist[s] direct detailing to individual local physicians and doctor’s offices.” Kroger Mot. at 5 (discussing Lembke Rep. at 101). This is simply false. Lembke’s sixth opinion refers to Kroger, by name, numerous times, in discussing the welcome Kroger extended to marketers from Purdue, Lembke Rep. at 119; Kroger’s failure to correct the “misinformation” that Purdue spread among its pharmacies through such marketing, *id.* at 120; and Kroger’s participation in the promotion of inaccurate opioids messaging through the NACDS, together with other national chain pharmacies, as well as manufacturers and distributors, *id.* at 126.

Moreover, Lembke’s sixth opinion discusses not just (or even primarily) “the internal workings of any particular pharmacy,” MDL ECF No. 4000, 622:3–5 (Court’s precis of *Daubert* ruling), but rather the extent to which pharmacies “leveraged their unique and pivotal position in the opioid supply chain to contribute to the unprecedented and unchecked flow of opioid pain pills into the community,” Lembke Rep. at 100, by means including abetting Purdue’s marketing, engaging in their own marketing through “advocacy” groups like the NACDS, and turning a blind eye to the insufficiency of their policies and procedures to guard against diversion, *see id.* While Plaintiff agrees that, under the Court’s Track Three ruling, Lembke may not testify that any particular pharmacy’s business practices “precluded a ‘red flag’ examination,” Lembke *may* testify: (1) that a pharmacy should investigate “red flags” of diversion; (2) that failing to do so

leads to abuse and diversion; and, critically, (3) as to the “efficacy and effects” of a defendant’s “policies and procedures,” MDL ECF No. 4000 at 622:3–5, that policies and procedures designed to detect red flags were in fact insufficient for that purpose, *see id.* at 636:17–18 (allowing such testimony as to Walmart in Track Three) – not to mention the vast amount of other material contained in Lembke’s sixth opinion that has nothing to do with whether a particular pharmacy’s business practices and “internal workings,” *id.* at 622:23–24, properly incentivized red-flag detection.

**B. Changed Circumstances Warrant a Different Result with Respect to Marketing Causation than in Tracks One and Three.**

Although Plaintiff agrees that this Court’s prior MDL rulings presumptively apply to all cases in the MDL, the Court has recognized that, where a party “can show that the particular circumstances of an individual case warrant a revision,” *In re Nat’l Prescription Opiate Litig.*, No. 17-md-2804, 2020 WL 6450290, at \*1 (N.D. Ohio Nov. 3, 2020), the Court’s prior rulings are subject to modification. In this case, new evidence warrants modification of the Court’s prior order regarding Dr. Lembke’s qualifications to opine about marketing causation.

Specifically, the record now reflects two substantial pieces of evidence demonstrating that governments and academics alike recognize Lembke’s qualification to speak on the causes of the opioid epidemic, including the pharmaceutical industry’s marketing:

- Lembke’s co-authorship of a report from the Stanford–*Lancet* Commission on the North American Opioid Crisis entitled, “Responding to the opioid

crisis in North America and beyond: recommendations of the Stanford-*Lancet* Commission,” published February 2, 2022.<sup>4</sup> As Dr. Lembke explains, she was selected to serve as a member of the Commission in 2020. *See* Lembke Rep. at 5. “The Commission Report specifically identifies and describes the role of the marketing and promotional conduct of the entities that comprise the chain of prescription opioid distribution, including manufacturers, distributors, and pharmacies, as a cause of the opioid epidemic.” *Id.*

- Two invitations extended to Lembke to speak on the opioid epidemic, *including its causes*, by governmental bodies: the Administrative Office of the Kentucky Courts, and the Ministerial Assistant to the Associate Minister of Mental Health and Addictions of Edmonton, Canada. *See id.* at 6. The Kentucky courts’ invitation expressly acknowledged Lembke’s “expertise” in asking her to speak on the “*origins, sociology, and current status*” of the opioid epidemic. *Id.* (emphasis added).

In addition to the material presented to the Court for the first time in Track Three (which, Plaintiff acknowledges, the Court found insufficient grounds, standing alone, to reconsider its Track One ruling), these two pieces of evidence make plain that, in the world outside the courtroom, Lembke is an acknowledged expert on the causes of the opioid epidemic, including on the causal role of the industry’s false and misleading

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<sup>4</sup> Available at [https://doi.org/10.1016/S0140-6736\(21\)02252-2](https://doi.org/10.1016/S0140-6736(21)02252-2).

promotional activities. Indeed, this additional evidence was presented to Judge Breyer in CT4, and, based on the record before him, he found that Dr. Lembke was qualified to opine on the effects of Defendants' marketing practices. *See* Order on *Daubert* Motions, *City & County of San Francisco v. Purdue Pharma*, No. 18-cv-07591-CRB (N.D. Cal. May 6, 2022) (ECF No. 1297 at 1).

Continuing to adhere to the Court's prior rulings in light of Lembke's co-authorship of the Stanford-*Lancet* Commission's report, in particular, would have the perverse consequence that qualifications acceptable to a purpose-built commission of specialists would be deemed unacceptable for a lay jury to even weigh for itself. This is precisely contrary to *Daubert*'s purpose: to ensure that juries hear real-world experts discuss their real-world expertise. *See Kumho Tire Co. Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999) ("The objective of [*Daubert*'s gatekeeping] requirement . . . is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."). Qualifications acceptable to governments and academics across the continent are properly submitted to a jury for its own evaluation.

### CONCLUSION

The Court should deny Kroger's motion. Specifically, the Court should: (1) deny the motion with respect to Dr. Courtwright and hold the challenged opinions admissible; (2) deny the with respect to Mr. Rafalski and hold his opinions concerning the Chemical Handler's Manual admissible; (3) either reconsider its prior rulings as applied to

Lembke's marketing causation opinions and find all of the challenged testimony admissible, or, in the alternative, adhere to the narrow limits of its prior rulings on that issue and exclude only the material previously excluded; and (4) with the exception of the one clause that was the subject of a prior ruling, deny the motion with respect to Dr. Lembke's pharmacy practice opinions.

Dated: March 9, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 9, 2023, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system and may be obtained by using the CM/ECF system. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF system.

/s/Peter H. Weinberger  
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